

REMARKS

Reconsideration of the rejections based upon the foregoing amendments and the following remarks is respectfully requested.

- A. **Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Bodai (US 4,929,426). Claims 2-4 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bodai in view of Diebold (US 5,437,999), Douglas (US 6,001,239), Drummond (US 5,863,400) or White (US 5,243,516).**

Claim 1, as amended herein, specifically requires the steps of :

- “b) applying a first signal to the measurement electrode;
- c) measuring a first response to the first signal;
- d) using the first response to produce an indication of a temperature of the biological fluid;
- e) applying a second signal to the measurement electrode;
- f) measuring a second response to the second signal to produce an indication of the concentration of the medically significant component; and
- g) determining a temperature-corrected concentration of the medically significant component based upon the first and second responses.”

It is respectfully submitted that the Bodai reference does not teach or suggest the above-recited elements of Applicants' claim 1.

As recited in the Office Action, Bodai teaches the use of a thermal sensing element 42 “in close proximity to the electrodes to permit the correction of the measurement for variations in temperature” (OA page 2, ¶3). Bodai therefore not only does not show the above recited elements of Applicants' claim 1, which requires that the same measurement electrode be used to determine an indication of a temperature of the biological fluid and an indication of the

concentration of the medically significant component, but instead teaches directly away from Applicants' amended claim 1. In stark contrast, Bodai teaches that a separate thermistor (thermal sensing element 42) should be placed near the measurement electrode in order to determine the temperature of the sample. It is therefore respectfully submitted that Applicants' claim 1 is allowable over the references of record.

Claim 2 depends from claim 1 and therefore includes all of the limitations of claim 1. The Office Action does not allege that any of the secondary references, either alone or in combination, cure the deficiency in Bodai outlined above. It is therefore respectfully submitted that claim 2 is allowable over the references of record for the same reasons set forth above with respect to claim 1.

Claims 3 and 4 have been cancelled herein, therefore their rejection under 35 U.S.C. §103(a) is now considered moot.

B. Claims 5-17, 20 and 22-26 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bodai in view of Diebold (US 5,437,999), Douglas (US 6,001,239), Drummond (US 5,863,400) or White (US 5,243,516), and further in view of Doss and de Vries.

Claims 5-7 depend from claim 1 and therefore include all of the limitations of claim 1. The Office Action does not allege that any of the secondary references cure the deficiency in Bodai outlined above. It is therefore respectfully submitted that claims 5-7 are allowable over the references of record for the same reasons set forth above with respect to claim 1.

The Office Action alleges that "[i]t would have been obvious to one of ordinary skill in the art to incorporate the temperature measurement method of Doss and the hematocrit measurement method of de Vries into the Bodai method because of the ability to measure the temperature and hematocrit without providing anything more than the electrodes already present

and an AC signal generator/analyzer as shown by Doss and de Vries” (Office Action, page 6, lines 14-18). Applicants offer the following multiple reasons why the cited combination does not make the claimed invention obvious.

Bodai teaches away by requiring a separate thermistor and Doss does not teach the measurement of the ambient temperature of a sample under test

The Bodai reference is cited to show that it was recognized in the art that temperature variation is something that needs to be measured and corrected for when measuring blood pH. However, Bodai actually teaches directly away from the claimed invention by teaching that the temperature of the sample should be measured using a silicon thermistor physically placed next to the measurement electrodes (see Column 10, lines 50-61), rather than using the measurement electrode to also measure the temperature of the sample. The Doss reference also does not teach the measurement of ambient sample temperature using AC excitation, but rather the active heating of a sample using AC excitation and controlling the amount of heating by monitoring the phase shift of the AC signal that is input to the antenna. Furthermore, Doss teaches this effect in a subcutaneous antenna implanted in (phantom) human tissue, not in a blood sample under test that was the subject of testing in Bodai.

Both Doss and de Vries use electrode configurations that are not compatible with Bodai

The implantable antenna of Doss includes electrodes consisting of two parallel rows of cylindrical pins embedded in (phantom) human tissue. These electrodes are coupled to the excitation and measurement electronics using a pair of antennas held in close proximity to one another. The measurement system of de Vries uses a 4 electrode tetrapolar impedance cell to

make hematocrit measurements. By contrast, Bodai teaches the use of an electrochemical measurement cell having a two electrode configuration. The Office Action alleges that it would be obvious to incorporate the measurements of Doss and de Vries with the electrochemical measurement cell of Bodai because of "the ability to measure the temperature and hematocrit without providing anything more than the electrodes already present." It is respectfully submitted that nothing in the prior art of record shows that the measurement techniques of Doss and de Vries are usable with the significantly different electrode configurations of Bodai. Furthermore, there is no teaching or suggestion in the prior art, nor an expectation of success, that the techniques used with the Doss parallel cylindrical pins or the de Vries tetrapolar impedance cell could be translated to the two electrode arrangements taught by Bodai. For example, the Doss electrode configuration, arrangement and size are important, since they contribute to the measured resistance, and the disclosed electrode arrangement bears no similarity to any of the electrodes taught by Bodai. Similarly, de Vries teaches that "[t]o guarantee a homogeneous electrical field distribution, the distance between the electrodes (10mm) was chosen to be more than twice the radius of the conductivity cell (4mm)" (de Vries, p.466). This is significantly larger than the electrode size of electrochemical blood glucose biosensors of the type taught by Bodai, and the blood sample volumes used by such biosensors would not cover a four electrode configuration of this scale.

It is not obvious to use DC and AC in a test using reagents

The biosensors of Bodai all comprise electrochemical cells that use DC signals to test for analytes, wherein the DC responses are generated via reactions (usually enzymatic) that require reagents. The AC signal responses detected by Doss and de Vries are generated directly from

the parameters of interest (temperature for Doss and hematocrit for de Vries): they are direct measurements of physical and physico-chemical properties without a specifying reagent. There is no teaching, suggestion or motivation in the art, nor would it be obvious to try, to use both DC signals and signals having an AC component together in the same environment, in the presence of a reagent, and with the same electrodes. It is recognized by Applicants that claims 8-17, 20 and 22-26 do not require a DC signal or a reagent, but the Bodai reference relates to DC tests conducted in the presence of a reagent, therefore it would not be obvious to use the AC methods of Doss and de Vries, which do not use reagents, with these DC reagent-based tests. Therefore, one skilled in the art would not be motivated to combine the various tests as suggested by the Examiner, and the combination of references relied upon in the Office Action do not render Applicant's invention obvious.

The Bodai system already provides for the measurement of temperature

In light of the lack of teaching in the combined references of how any of the techniques of Doss and de Vries might be workably incorporated into the radically different electrode structure of Bodai, coupled with the fact that Bodai already provides for a simple method for measuring the temperature of the sample, one of ordinary skill in the art would not be motivated to attempt the combination of radically disparate elements as suggested by the Office Action.

It is therefore respectfully submitted that Applicants' claim 8, which specifically requires the steps of :

- "b) applying a first temperature measurement signal having an AC component to the measurement electrode;
- c) measuring a first AC temperature measurement response to the first temperature measurement signal;

- d) using the first AC temperature measurement response to produce an indication of a temperature of the biological fluid;
- e) applying a first concentration measurement signal to the measurement electrode;
[and]
- f) measuring a first concentration measurement response to the first concentration measurement signal to produce an indication of the concentration of the medically significant component”

is not shown or suggested by the references of record.

Claims 9-17 and 20 depend from claim 8 and therefore include all of the limitations of claim 8. It is therefore respectfully submitted that claims 9-17 and 20 are allowable over the references of record for at least the same reasons set forth above with respect to claim 8.

It is further respectfully submitted that Applicants’ claim 22, which specifically requires the steps of :

- “b) applying a first temperature measurement test signal having an AC component to the measurement electrode, the first temperature measurement test signal having a first frequency;
- c) measuring at least a first AC temperature measurement response to the first temperature measurement test signal;
- d) determining a temperature value of the biological fluid using the first AC temperature measurement response;
- e) applying a first concentration measurement signal to the measurement electrode;
[and]
- f) measuring at least a first concentration measurement response to the first concentration measurement signal to produce an indication of the glucose concentration of the biological fluid”

is not shown or suggested by the references of record.

Claims 23-26 depend from claim 22 and therefore include all of the limitations of claim 22. It is therefore respectfully submitted that claims 23-26 are allowable over the references of record for at least the same reasons set forth above with respect to claim 22.

C. Claims 1-26 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 22-38 and 44-46 of U.S. Patent No. 6,645,368 in view of Bodai, Doss and de Vries.

The Office Action alleges that “[t]he instant claims are of a scope that encompasses the patented claims except for the type of correction that is made based on the AC signal. However, Bodai clearly indicates that temperature is one parameter that needs (sic) to be taken into account and Doss and de Vries show the ability to measure the temperature and hematocrit without providing anything more than the electrodes already present and an AC signal generator/analyzer. Therefore, it would have been obvious to incorporate these types of corrections because of the need to apply corrections of these types in analysis methods” (Office Action, ¶8).

It is respectfully submitted that the present claims are not obvious in view of the cited claims in Beaty for the same reasons set forth above with respect to the rejection under 35 U.S.C. §103(a) (see section C hereinabove). The disclosures of Doss and de Vries are incompatible with the biosensor configurations of Bodai and Beaty. Bodai taught directly away from the use of the same electrode to measure both temperature and concentration. It is therefore respectfully submitted that the present claims are patentable without the provision of a terminal disclaimer.

For the foregoing reasons, Applicants respectfully submit that the present application is in condition for allowance, and respectfully request such action. Applicants respectfully request that the Examiner telephone the undersigned attorney for Applicants at 317-634-3456 if the Examiner does not find that all claims are in condition for allowance as presented herein.

Respectfully submitted,

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